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EXAMINER	
EREZO, DARWIN P	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/601,127
Filing Date: June 19, 2003
Appellant(s): SCHULER ET AL.

Guy Tucker
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 09/10/09 appealing from the Office action mailed 3/10/09.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application: 53-60.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

NEW GROUND(S) OF REJECTION

Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,727,546 to Clarke et al. in view of US 5,724,959 to McAughey et al.

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,727,546	CLARK et al.	3-1998
6,116,237	SCHULTZ et al.	9-2000
5,724,959	MCAUGHEY et al.	3-1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

Claims 53-55, 57 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,727,546 to Clarke et al.

(claim 53) Clarke discloses a method for aerosolizing a pharmaceutical formulation, the method comprising:

providing a valve **27** (valve portion 24) within an airway (the interior space of the device shown in Figs. 2(a) – 2(c)) leading to the lungs to prevent respiratory gases from flowing to the lungs when a user attempts to inhale (Fig. 2(a) shows the closed

position), and then permitting respiratory gasses to flow to the lungs (Fig. 2(b)) by opening the valve when a threshold actuating vacuum caused by the attempted inhalation exceeds the pressure of the spring biasing means **26**;

providing a flow regulator **23** within the airway, wherein the flow regulator varies the flow resistance through the airway to control the flow of respiratory gases (as seen between Figs. 2(b)-2(c)), wherein the flow resistance through the flow regulator is low when the respiratory gases are permitted to flow and increases when the vacuum generated by the user increases thereafter (see attached figure below); and

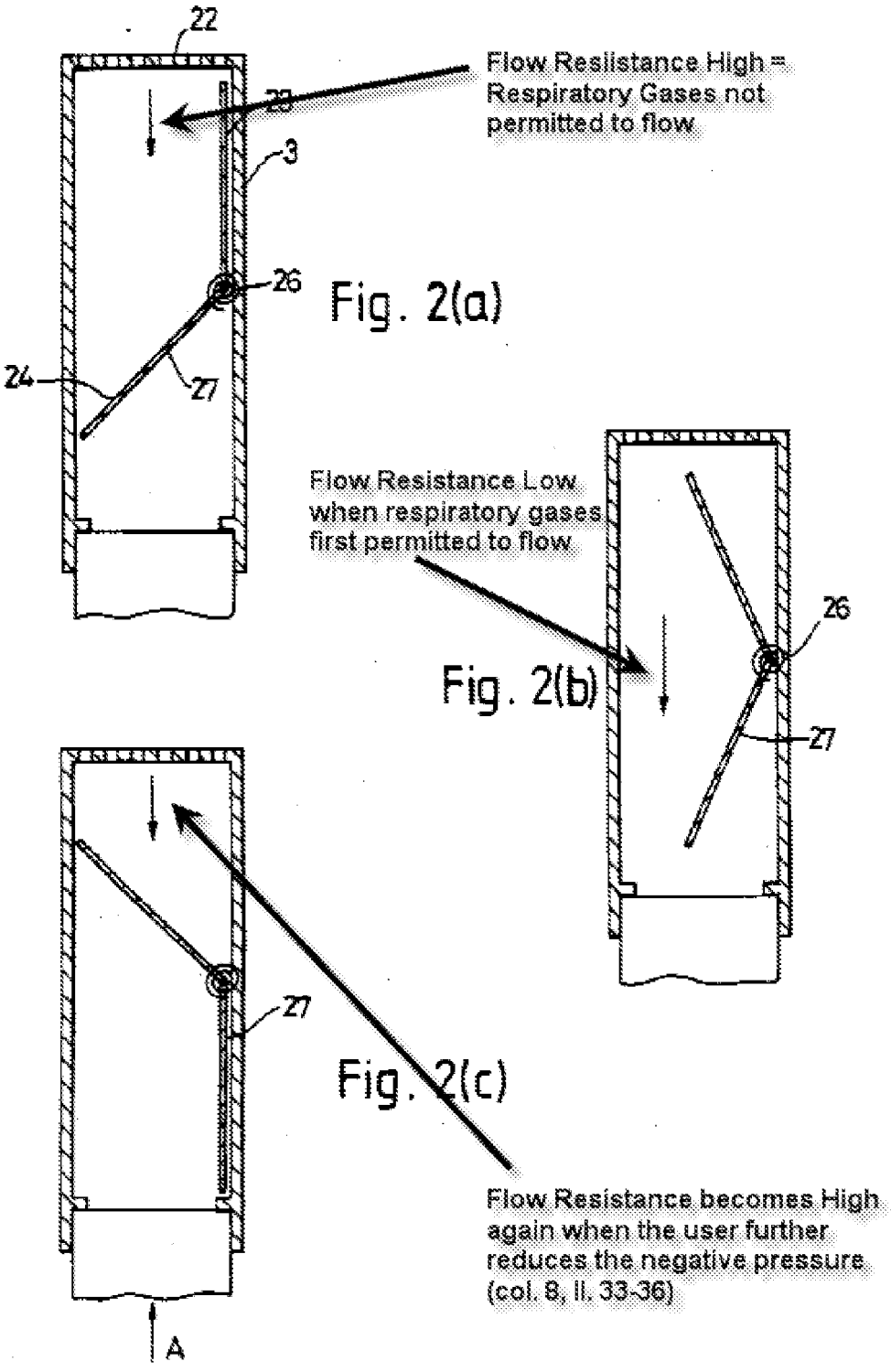
using the flow of respiratory gases to extract a pharmaceutical formulation from a receptacle **11** (shown in Fig. 1(a)) and to place said formulation within the flow of respiratory gases to form an aerosol.

(claim 54) Clark discloses the desired negative pressure created in the mouthpiece to be in the range of 0.1-20 mbar, which is equivalent to 0.1-20.29 cm H2O (see col. 5, lines 2-4).

(claim 55) The flow regulator **23** is fully capable of limiting the flow of gas to a rate that is less than a higher rate.

(claim 57) The flow regulator **23** regulates the size of the airway.

(claim 59) The valve **27** and the flow regulator **23** are arranged in series.


22
23
3
26
24
27
Flow Resistance High = Respiratory Gases not permitted to flow
Fig. 2(a)
Flow Resistance Low when respiratory gases first permitted to flow
26
27
Fig. 2(b)
27
A
Fig. 2(c)
Flow Resistance becomes High again when the user further reduces the negative pressure (col. 8, ll. 33-36)

Claim Rejections - 35 USC § 103

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke et al. in view of US 6,116,237 to Schultz et al.

Clarke discloses a desired flow rate of between 20-250 l/min. Clarke fails to teach the specific flow rate of 15 l/min. However, Schultz discloses that a flow rate of 15-60 l/min is required to provide a better delivery efficiency of powder medicaments (see abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methodology of Clarke to include the flow rate of 15 l/min because certain dry powder medicament require a lower flow rate for better delivery efficiency of the medicament into lungs.

Claims 58 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke et al.

(claim 58) Clarke teaches the embodiment of the flow regulator **23** shown in Figs. 2(a)-2(c) as a vane. However, Clarke discloses various other embodiment for the flow regulator, including a duck bill valve shown in Fig. 9(a). These are disclosed as equivalent structures known in the art. Therefore, since these embodiments were art-recognized equivalent at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute one embodiment for the other.

(claim 60) Clarke teaches the valve **27** and the flow regulator **23** being arranged in series, as shown in Figs. 2(a)-2(c). Clarke fails to teach a parallel arrangement. However, it would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to modify the arrangement from a

series arrangement to a parallel arrangement because Applicant has not disclosed that parallel arrangement provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the series arrangement or the claimed parallel arrangement because both arrangements perform the same function of regulating air flow to the patient. Furthermore, the applicant has not provided any criticality to a "parallel" arrangement since the applicant discloses that the invention could either have a series or parallel flow arrangement.

Therefore, it would have been obvious matter of design choice to modify the invention of Clarke to obtain the invention as specified in claim 60.

NEW GROUND(S) OF REJECTION

Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke et al. in view of US 5,724,959 to McAughey et al.

Clarke discloses all the limitations of the claim except for the airway having a parallel flow arrangement. However, providing an inhaler with a parallel flow arrangement is well known in the art. For example, McAughey discloses an inhaler **10** having a duct **32** defining an airway with baffles that break down the flow of air to multiple parallel directions (see Fig. 2, there are two parallel flow of air passing above and below the baffle 36; Fig. 5 also shows various parallel air flow defined in the baffles 68, 66). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Clarke to include a parallel flow arrangement by the addition of a

baffle since the baffle helps intercept or break down larger particles to help drug efficiency (see abstract of McAughey).

(10) Response to Argument

The appellant argued that Clarke fails to teach a threshold valve and flow regulator as claimed. It was argued that the vane 27, which is being interpreted by the examiner as the threshold valve, is not disclosed as a threshold valve. However, this is not found persuasive as the vane 27 of Clarke is inherently a threshold valve.

Clarke discloses a breath-actuated powder inhaler that requires the user to inhale to initiate the delivery of the medicament. The inhaler is provided with a vane 27 that is coupled to a spring 26. The spring 26 biases the vane to a closed configuration, as shown in Fig. 2(a); see col. 8, ll. 20-26. When a user inhales through the mouthpiece, a negative pressure is created in the space between the mouthpiece and vane 27. When this negative pressure is sufficient to overcome the biasing pressure of the spring 26, the vane 27 pivots about a hinge 25 to allow the passage of air/medicament from the inhaler to the user. The point at which the negative pressure created by the inhalation overcomes the biasing pressure of the spring 26 is being viewed by the examiner as the “threshold point”. This threshold feature is implicit in the operation of vane 27.

Independent claim 53 recites "providing a valve...to prevent respiratory gases from flowing to the lungs when a user attempts to inhale". It is the examiner’s position that the vane 27 of Clarke acts in the same manner as cited in the claims when a user’s initial inhalation pressure is not sufficient to overcome the biasing pressure provided by

the spring 26. An example of this condition would be a user inhaling very slowly, which would prevent the buildup of negative pressure that is sufficient to overcome the biasing pressure of spring 26. Also note that this claim limitation does not state what pressure is required to overcome the pressure of the valve.

The appellant also argued that Clarke fails to teach another limitation of claim 53, which is "wherein the flow resistance through the flow regulator is low when the respiratory gases are permitted to flow and increases when the vacuum generated by the user increases thereafter". First, it should be noted that the claim does not specifically state the point at which the respiratory gases are permitted to flow, i.e. it does not state that the flow resistance through the flow regulator is low when the respiratory gases are first permitted to flow (as argued in page 5 of the Appeal Brief). Thus, it could be at any point in which gases are permitted to flow to the user. Second, Fig. 2(b) of Clarke discloses a position for flow regulator 23 in which gas is "permitted to flow", wherein the flow resistance is at its lowest (col. 8, ll. 27-32, the air flow is at its maximum/less resistance). When a user further decreases the negative pressure at the mouthpiece by inhaling faster (synonymous to increasing vacuum pressure), the flow regulator 23 rotates along with vane 27 to reduce flow of air (col. 8, ll. 33-36), thus, increasing the flow resistance. This type of operation is crucial to inhaler devices that regulate the rate of patient inspiration in order to provide the optimum drug deliver efficiency (col. 1, ll. 5-6; col. 5, ll. 31-33).

With regards to claim 58, the appellant merely states that "Clarke et al fails to disclose or teach the duckbill valve recited in the claim." However, the appellant did not

fully address rejections provided by the examiner. As provided in the rejections above, Clarke discloses another embodiment that utilizes a duckbill valve instead of a vane valve. Thus, the valves are known equivalents and therefore one of ordinary skill in the art would have found it obvious to use these valves interchangeably with an expectation of achieving similar results regardless of which valve was used. Duckbill valves would be readily available to one of ordinary skill in the art.

With regards to claim 60, the examiner provided an obvious design choice motivation in the rejections for modifying the series arrangement of Clarke to a parallel arrangement. It is noted that the applicant discloses in the specification (and claims) that the arrangement can be in series or parallel. Therefore, there is no criticality provided for either arrangement, and that choosing a specific arrangement would be a mere obvious design choice. In addition, the examiner has provided a new rejection for claim 60 to reinforce the fact that having a series or parallel flow arrangement is well known in the respiratory art.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer

exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

/Darwin P. Erezo/
Primary Examiner, Art Unit 3773

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/Angela D Sykes/

Director, Technology Center 3762

Conferees:

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773

/Janet C. Baxter/
TC 3700 TQAS